42-077-00181

B|BRAUN

January 28, 2021

Mr. Mark Wejkszner
Pennsylvania Department of Environmental Protection
2 Public Square
Wilkes-Barre, PA 18711-0790

Office of Air Enforcement and Compliance Assistance (3AP20)
USEPA, Region III
1650 Arch Street
Philadelphia, PA 19103-2029

Re: Submittal of 40 CFR Part 63.10(e)(3)(i) and (vi)
Summary Report – Excess Emissions and CMS Performance Report
For Units Subject to 40 CFR Part 63, Subpart O
For the period of July 1, through December 31, 2020
B. Braun Medical, Inc., Allentown, Pennsylvania

To Whom it May Concern:

Pursuant to 40 CFR Part 63, Subparts A and O, B. Braun Medical, Inc. (B. Braun) is submitting the attached completed semi-annual summary report. B. Braun's facility in Allentown, Pennsylvania is subject to the Ethylene Oxide Emission Standards for Sterilization Facilities promulgated at 40 CFR Part 63, Subpart O. During the reporting period, the total duration of excess emissions or process control system parameter exceedances was less than 1 percent of the total operating time, and the CMS downtime was less than 5 percent of the total operating time. Therefore, in accordance with 40 CFR §63.10(e)(3)(vii), this reporting is addressed through the summary report format.

The control devices for B Braun's ethylene oxide sterilization process were replaced on September 21, 2020. Therefore, this report covers July 1 through September 21 for the previous control device configuration, and September 21 through December 31 for the replacement control device.

If you have any questions or require additional information please do not hesitate to contact me at (610) 596-2474.

Sincerely,

Eric Geder
Environmental Health Safety/Security Manager, Allentown Operations

cc: Enf. Programs Sec.

SUMMARY REPORT, JULY 1 – SEPTEMBER 21, 2020 –EXCESS EMISSIONS AND CONTINUOUS MONITORING SYSTEM PERFORMANCE

1.0 Name and Address (physical location) of the Source (40 CFR 63.10(e)(3)(vi)(A)):

B. Braun Medical, Inc.
901 Marcon Blvd.
Allentown, PA 18109

2.0 Identification of Each HAP Monitored at the Source (40 CFR 63.10(e)(3)(vi)(B)):

40 CFR Part 63, Subpart O (Subpart O) regulates the control of the hazardous air pollutant (HAP) ethylene oxide. Subpart O provides for parametric monitoring in lieu of emission monitoring of ethylene oxide at the source. The following table identifies the parameters monitored in accordance with Subpart O:

TABLE 2.1: REGULATED HAP AND ASSOCIATED PARAMETRIC MONITORING VARIABLES

HAP	Monitored Parameters	Citation	Type of Monitoring System
Ethylene Oxide	Scrubber Tank Level	63.364(b)	CPMS
	Oxidation Temperature	63.364(c)	CPMS

3.0 Reporting Period (40 CFR 63.10(e)(3)(vi)(C)):

The reporting period covered by this report is from July 1 through September 21, 2020.

4.0 Description of Process Units (40 CFR 63.10(e)(3)(vi)(D)):

The B. Braun facility manufactures surgical and medical instruments that are sterilized during the manufacturing process. The sterilization procedure utilizes ethylene oxide (ETO) within eight (8) ETO sterilization chambers (Units 101 – 108), which operate on a batch-cycle basis. From each sterilization chamber, the sterilized devices are directed to a common aeration room (Unit 110). The sterilization chambers and the aeration room are vented to emissions control equipment in accordance with Subpart O. Each sterilization chamber is controlled by a common Deoxx unit, which employs a wet scrubbing technique for treatment of ETO emissions and achieves a 99% emission reduction. Consistent with Subpart O, once the majority of the gas stream has been sent to the Deoxx unit, a small amount of residual, low concentration ETO gas is vented from the rear exhaust vent of each sterilization chamber. ETO emissions from the aeration room are controlled by the Donaldson Catalytic Oxidizer, which satisfies the emission standards specified in 40 CFR §63.362(d).

5.0 Emission and Operating Parameter Limitations Specified in Standard (40 CFR 63.10(e)(3)(vi)(E)):

The applicable emission limitations for sterilization facilities are detailed in 40 CFR 63.362 and are provided in Table 5.1 below.

TABLE 5.1: SUBPART O STANDARDS FOR B. BRAUN

HAP (Source)	Standard
Ethylene Oxide (Sterilization Chamber Vent)	99% emissions reduction
Ethylene Oxide (Aeration Room Vent)	99% emissions reduction or 1 ppmv, whichever is less stringent

In accordance with 40 CFR 63.364 and 63.365, relevant operating parameter levels for scrubber tank level and oxidation temperature were established during performance testing.

6.0 Monitoring Equipment Manufacturer and Model Number (40 CFR 63.10(e)(3)(vi)(F)) and Date of Latest CMS Certification or Audit (40 CFR 63.10(e)(3)(vi)(G)):

Refer to Table 6.1 and Table 6.2 for the monitoring equipment manufacturer and model number and date of last CMS certification or audit.

TABLE 6.1: DEOXX UNIT MONITORING EQUIPMENT MANUFACTURER, MODEL NUMBER, AND LATEST CERTIFICATION DATE

Monitored Parameter	Equipment Manufacturer	Model Number	Date of Last CMS Audit or Certification
Scrubber Liquor Level	N/A	N/A	September 2020

TABLE 6.2: DONALDSON CATALYTIC OXIDIZER MONITORING EQUIPMENT MANUFACTURER, MODEL NUMBER, AND LATEST CERTIFICATION DATE

Monitored Variables	Equipment Manufacturer	Model Number	Date of Last CMS Audit or Certification
Oxidation Temperature	MINCO	TC359JU612972	June 2020

7.0 Total Operating Time for Each Source (40 CFR 63.10(e)(3)(vi)(H)):

Please refer to Attachment 1 and Attachment 2 for total operating time for each source during the reporting period.

8.0 Control System Parameter Data Summary (40 CFR 63.10(e)(3)(vi)(I)):

Please refer to Attachments 1 and Attachment 2 for the control system parameter data summary for this reporting period.

9.0 CMS Performance Summary (40 CFR 63.10(e)(3)(vi)(J)):

Please refer to Attachment 2 for the CMS performance summary for this reporting period.

10.0 Description of Changes in CMS, Processes or Controls Since Previous Reporting Period (40 CFR 63.10(e)(3)(vi)(K)):

No changes in the CMS, process, or controls have occurred since the previous reporting period.

11.0 Certification and Report Date (40 CFR 63.10(e)(3)(vi)(L) and (M)):

I certify, based on a reasonable inquiry of the persons responsible for preparing this semi-annual report that the information provided is, to the best of my knowledge and belief true, accurate, and complete.

Rex L Boland

Rex Boland
Vice President/General Manager, PA Operations

Report Date: 1-28-21

SUMMARY REPORT, SEPTEMBER 21 - DECEMBER 31, 2020 –EXCESS EMISSIONS AND CONTINUOUS MONITORING SYSTEM PERFORMANCE

3.0 Name and Address (physical location) of the Source (40 CFR 63.10(e)(3)(vi)(A)):

B. Braun Medical, Inc.
901 Marcon Blvd.
Allentown, PA 18109

4.0 Identification of Each HAP Monitored at the Source (40 CFR 63.10(e)(3)(vi)(B)):

40 CFR Part 63, Subpart O (Subpart O) regulates the control of the hazardous air pollutant (HAP) ethylene oxide. Subpart O provides for parametric monitoring in lieu of emission monitoring of ethylene oxide at the source. The following table identifies the parameters monitored in accordance with Subpart O:

TABLE 2.1: REGULATED HAP AND ASSOCIATED PARAMETRIC MONITORING VARIABLES

HAP	Monitored Parameters	Citation	Type of Monitoring System
Ethylene Oxide	Oxidation Temperature	63.364(c)	CPMS

3.0 Reporting Period (40 CFR 63.10(e)(3)(vi)(C)):

The reporting period covered by this report is from September 21 through December 31, 2020.

4.0 Description of Process Units (40 CFR 63.10(e)(3)(vi)(D)):

The B. Braun facility manufactures surgical and medical instruments that are sterilized during the manufacturing process. The sterilization procedure utilizes ethylene oxide (ETO) within eight (8) ETO sterilization chambers (Units 101 – 108), which operate on a batch-cycle basis. From each sterilization chamber, the sterilized devices are directed to a common aeration room (Unit 110). The sterilization chambers and the aeration room are vented to emissions control equipment in accordance with Subpart O. The sterilization chambers and aeration room are controlled by a common Anguil System, which employs a peak shaver and catalytic oxidizer for treatment of ETO emissions and achieves greater than a 99% emission reduction and satisfies the emissions standards specified in 40 CFR §63.362(d). Consistent with Subpart O, once the majority of the gas stream has been sent to the Anguil System, a small amount of residual, low concentration ETO gas is vented from the rear exhaust vent of each sterilization chamber.

5.0 Emission and Operating Parameter Limitations Specified in Standard (40 CFR 63.10(e)(3)(vi)(E)):

The applicable emission limitations for sterilization facilities are detailed in 40 CFR 63.362 and are provided in Table 5.1 below.

TABLE 5.1: SUBPART O STANDARDS FOR B. BRAUN

HAP (Source)	Standard
Ethylene Oxide (Sterilization Chamber Vent)	99% emissions reduction
Ethylene Oxide (Aeration Room Vent)	99% emissions reduction or 1 ppmv, whichever is less stringent

In accordance with 40 CFR 63.364 and 63.365, the relevant operating parameter level for oxidation temperature (310 F) to the inlet of the catalyst bed was established during performance testing completed on December 15, 2020 and by the manufacturer recommendation prior to performance testing. The final report for the performance testing is pending completion and submission.

6.0 Monitoring Equipment Manufacturer and Model Number (40 CFR 63.10(e)(3)(vi)(F)) and Date of Latest CMS Certification or Audit (40 CFR 63.10(e)(3)(vi)(G)):

Refer to Table 6.1 for the monitoring equipment manufacturer and model number and date of last CMS certification or audit.

TABLE 6.1: ANGUIL CATALYTIC OXIDIZER MONITORING EQUIPMENT MANUFACTURER, MODEL NUMBER, AND LATEST CERTIFICATION DATE

Monitored Variables	Equipment Manufacturer	Model Number	Date of Last CMS Audit or Certification
Oxidation Temperature	Pyromation	K68U-048-00-8HN31	June 2020/ December 2020

7.0 Total Operating Time for Each Source (40 CFR 63.10(e)(3)(vi)(H)):

Please refer to Attachment 1 and Attachment 2 for total operating time for each source during the reporting period.

8.0 Control System Parameter Data Summary (40 CFR 63.10(e)(3)(vi)(I)):

Please refer to Attachments 1 and Attachment 2 for the control system parameter data summary for this reporting period.

9.0 CMS Performance Summary (40 CFR 63.10(e)(3)(vi)(J)):

Please refer to Attachment 2 for the CMS performance summary for this reporting period.

10.0 Description of Changes in CMS, Processes or Controls Since Previous Reporting Period (40 CFR 63.10(e)(3)(vi)(K)):

The Anguil System has replaced the Donaldson Catalytic Oxidizer and Wet Scrubber Deoxx Unit previously used to control emissions from the sterilization chambers and aeration room. The MINCO CMS used to monitor oxidation temperature has been replaced by a Pyromation monitoring device. No changes have been made to the sterilization process.

11.0 Certification and Report Date (40 CFR 63.10(e)(3)(vi)(L) and (M)):

I certify, based on a reasonable inquiry of the persons responsible for preparing this semi-annual report that the information provided is, to the best of my knowledge and belief true, accurate, and complete.

Rex A. Boland

Rex Boland
Vice President/General Manager, PA Operations

Report Date: 1-28-21

Attachment 1
Summary of Excess Emissions

Donaldson Catalytic Oxidizer Unit (Aeration Room Vent)
B. Braun Medical Inc. - Allentown, PA
MACT Parameter Exceedence Summary for Reporting Period: 07/1/2020-09/21/2020

Attachment # 1

Donaldson Catalytic Oxidizer Unit Source Operating Time = 103457 [minutes]			Excess Emissions Summary							
Monitored Parameter	**Limit**	**Averaging Time**	**Startup or Shutdown (min)**	**Control Equipment Malfunction (min)**	**Process Equipment Malfunction (min)**	**Other Known Cause (min)**	**Other Unknown Cause (min)**	**Total Duration of Excess Emissions (min)**	**% Excess [a,b] Emissions**	**Is the % Excess Emissions Greater than 1%?**
Minimum Oxidation Temperature	253/258 deg F	15-minute values or shorter, compute and record 24-hour average, when catalytic oxidizer is operated	N/A	N/A	N/A	N/A	N/A	0	0.00	NO

[a] Excursions caused by Malfunction events are not counted toward the Excess Emissions total duration and 1% full Excess Emission Report threshold level as the limits do not apply during Malfunction events [63.362(b)]

[b] Per §63.10(e)(3)(vii) excess emissions and monitor downtime was calculated based on the total duration of excess emissions or monitor downtime per the total control equipment operating time during the reporting period

Donaldson Catalytic Oxidizer Unit Operating Time
(minutes per semi-annual time period): 103,457

DEOXX Unit (Sterilization Chamber Vent)
B. Braun Medical Inc. - Allentown, PA
MACT Parameter Exceedence Summary for Reporting Period: 07/1/2020-09/21/2020

Attachment # 1

DEOXX Unit Source Operating Time = 120233 [minutes]			Excess Emissions Summary							
Monitored Parameter	**Limit**	**Averaging Time**	**Startup or Shutdown (min)**	**Control Equipment Malfunction (min)**	**Process Equipment Malfunction (min)**	**Other Known Cause (min)**	**Other Unknown Cause (min)**	**Total Duration of Excess Emissions (min)**	**% Excess [a,b] Emissions**	**Is the % Excess Emissions Greater than 1%?**
Maximum Scrubber Liquor Level	126 inches	N/A	N/A	N/A	N/A	N/A	N/A	0	0.00	NO

[a] Excursions caused by Malfunction events are not counted toward the Excess Emissions total duration and 1% full Excess Emission Report threshold level as the limits do not apply during Malfunction events [63.362(b)]

[b] Per §63.10(e)(3)(vii) excess emissions and monitor downtime was calculated based on the total duration of excess emissions or monitor downtime per the total control equipment operating time during the reporting period

DEOXX Unit Operating Time

(minutes per semi-annual time period): 120,233

Anguil Catalytic Oxidizer Unit
B. Braun Medical Inc. - Allentown, PA
MACT Parameter Exceedence Summary for Reporting Period: 09/21/2020-12/31/2020

Attachment # 1

Anguil Catalytic Oxidizer Unit Source Operating Time = 143303 [minutes]			Excess Emissions Summary							
Monitored Parameter	**Limit**	**Averaging Time**	**Startup or Shutdown (min)**	**Control Equipment Malfunction (min)**	**Process Equipment Malfunction (min)**	**Other Known Cause (min)**	**Other Unknown Cause (min)**	**Total Duration of Excess Emissions (min)**	**% Excess [a,b] Emissions**	**Is the % Excess Emissions Greater than 1%?**
Minimum Inlet Oxidation Temperature to Catalyst Bed	310 deg. F	15-minute values or shorter, compute and record 24-hour average, when catalytic oxidizer is operated	N/A	N/A	N/A	N/A	N/A	0	0.00	NO

[a] Excursions caused by Malfunction events are not counted toward the Excess Emissions total duration and 1% full Excess Emission Report threshold level as the limits do not apply during Malfunction events [63.362(b)]

[b] Per §63.10(e)(3)(vii) excess emissions and monitor downtime was calculated based on the total duration of excess emissions or monitor downtime per the total control equipment operating time during the reporting period

Anguil Catalytic Oxidizer Unit Operating Time
(minutes per semi-annual time period): 143,303

Attachment 2
CMS Performance Summaries

Donaldson Catalytic Oxidizer Unit (Aeration Room Vent)
B. Braun Medical Inc. - Allentown, PA
MACT Parameter Monitor Performance Summary for Reporting Period: 07/1/2020-09/21/2020

Attachment # 2

Donaldson Catalytic Oxidizer Unit Source Operating Time = 103457 [minutes]			CMS Downtime Summary							
Monitored Parameter	**Limit**	**Averaging Time**	**Monitoring Equipment Malfunctions** (min)	**Non-Monitoring Equipment Malfunctions** (min)	**"Non-(a) Routine" QA/QC Calibrations** (min)	**Other Known Causes** (min)	**Other Unknown Causes** (min)	**Total Duration of CMS Downtime** (min)	**% CMS Downtime**	**Is the % Excess Emissions Greater than 5%?**
Minimum Oxidation Temperature	253/258 deg F	15-minute values or shorter, compute and record 24-hour average, when catalytic oxidizer is operated	N/A	N/A	N/A	N/A	N/A	0	0.00	NO

Donaldson Catalytic Oxidizer Unit Operating Time (minutes per semi-annual time period): 103,457

DEOXX Unit (Sterilization Chamber Vent)
B. Braun Medical Inc. - Allentown, PA
MACT Parameter Monitor Performance Summary for Reporting Period: 07/1/2020-09/21/2020

Attachment # 2

DEOXX Unit Source Operating Time = 120233 [minutes]			CMS Downtime Summary							
Monitored Parameter	Limit	Averaging Time	Monitoring Equipment Malfunctions (min)	Non-Monitoring Equipment Malfunctions (min)	"Non-[a] Routine" QA/QC Calibrations (min)	Other Known Causes (min)	Other Unknown Causes (min)	Total Duration of CMS Downtime (min)	% CMS Downtime	Is the % Excess Emissions Greater than 5%?
Maximum Scrubber Liquor Level	126 inches	N/A	N/A	N/A	N/A	N/A	N/A	0	0 00	NO

DEOXX Unit Operating Time
(minutes per semi-annual time period): 120,233

Anguil Catalytic Oxidizer Unit
B. Braun Medical Inc. - Allentown, PA
MACT Parameter Monitor Performance Summary for Reporting Period: 09/21/2020-12/31/2020

Attachment # 2

Anguil Catalytic Oxidizer Unit Source Operating Time = 143303 [minutes]			CMS Downtime Summary							
Monitored Parameter	**Limit**	**Averaging Time**	**Monitoring Equipment Malfunctions** (min)	**Non-Monitoring Equipment Malfunctions** (min)	**"Non-(a) Routine" QA/QC Calibrations** (min)	**Other Known Causes** (min)	**Other Unknown Causes** (min)	**Total Duration of CMS Downtime** (min)	**% CMS Downtime**	**Is the % Excess Emissions Greater than 5%?**
Minimum Inlet Oxidation Temperature to Catalyst Bed	310 deg F	15-minute values or shorter, compute and record 24-hour average, when catalytic oxidizer is operated	N/A	N/A	N/A	N/A	N/A	0	0.00	NO

Anguil Catalytic Oxidizer Unit Operating Time
(minutes per semi-annual time period): 143,303